UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/007,890	01/23/2006	6066168	067448-0000004	5461

24201 7590 02/11/2008

FULWIDER PATTON LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 02/11/2008

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/008,619	05/07/2007	6066168		4093

24201 7590 02/11/2008

FULWIDER PATTON LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 02/11/2008

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

DO NOT USE IN PALM PRINTER

(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

PILLSBURY WINTHROP SHAW PITTMAN, LLP
P.O. BOX 10500
MCLEAN, VA 22102

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/007,890 & 90/008,619*.

PATENT NO. *6,066,168*.

ART UNIT *3993*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Office Action in Ex Parte Reexamination	Control No. 90/007,890 and 90/008,619	Patent Under Reexamination 6066168	
	Examiner Sara S. Clarke	Art Unit 3993	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

a☒ Responsive to the communication(s) filed on *23 March 2007 and 07 May 2007* . b☐ This action is made FINAL.
c☐ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire *2* month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Information Disclosure Statement, PTO/SB/08.
3. ☐ Interview Summary, PTO-474.
4. ☐ _____.

Part II SUMMARY OF ACTION

1a. ☒ Claims *1-18* are subject to reexamination.
1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been canceled in the present reexamination proceeding.
3. ☒ Claims *8-11 and 17* are patentable and/or confirmed.
4. ☒ Claims *1-7,12-16 and 18* are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ The drawings, filed on _____ are acceptable.
7. ☐ The proposed drawing correction, filed on _____ has been (7a)☐ approved (7b)☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   1☐ been received.
   2☐ not been received.
   3☐ been filed in Application No. _____ .
   4☐ been filed in reexamination Control No. _____.
   5☐ been received by the International Bureau in PCT application No. _____.
   * See the attached detailed Office action for a list of the certified copies not received.
9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.
10. ☐ Other: _____

cc: Requester (if third party requester)

DETAILED ACTION

Interpretation of Certain Claim Terms

1. In the decision of Trans Texas Holdings Corp., the court explained the proper method of claim construction during reexamination proceedings. In this decision, the court held as follows: "Claims are given 'their broadest reasonable interpretation, consistent with the specification, in reexamination proceedings.'" In re Trans Texas Holdings Corp. 498 F.3d 1290, 1298 (Fed. Cir. 2007), *quoting from* In re Yamamoto, 740 F.2d 1569, 1571 (Fed.Cir.1984). Citing to *Phillips v. AWH Corp.*, the same court further stated, "In Phillips, we held that while 'the specification [should be used] to interpret the meaning of a claim,' courts must not 'import[ ] limitations from the specification into the claim.'" Trans Texas Holdings Corp. at 1298, *quoting from* Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir.2005).

2. "When interpreting a claim, words of the claim are generally given their ordinary and accustomed meaning, unless it appears from the specification or the file history that they were used differently by the inventor." In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips at 1313.

3. "Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision. 'Where an inventor chooses to be his own lexicographer and to give terms uncommon meanings, he must set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change." Paulsen at 1480, quoting from Intellicall, Inc., v. Phonometrics, Inc., 952 F.2d 1384, 1387-88 (Fed.Cir.1992). On the other hand, "the specification may define claim terms 'by implication' such that the meaning may be 'found in or ascertained by a reading of the patent documents.'" Bell Atlantic Network services, Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001), quoting from Vitronics corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 and 1584 n. 6 (Fed. Cir. 1996).

4. "Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms

idiosyncratically, the court looks to 'those sources available to the public that show what a person of skill in the art would have understood the disputed claim language to mean.' Those sources include 'the words of the claims themselves, the remainder of the specification, the prosecution, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.'" (Citations omitted.) Phillips at 1314.

"longitudinally flexible"

5. At p. 22 of the patent owner's response submitted March 23, 2007 (POR), the patent owner advocated the following meaning for "longitudinally flexible": "flexible along its length to facilitate delivery to tortuous body lumens." At pp. 9 and 10 of the request filed in reexamination 90/008,619 (" '8619 request"), the requester advocated the following meaning: "flexible relative to the longitudinal axis."

6. With regard to the interpretation of "longitudinally flexible," the following evidence is within the record: the claims themselves, the usage of the term in the specification, the article by Duprat et al. entitled "Flexible Balloon-expanded Stent for Small Vessels," the declaration of Drs. Kahn and Segal, and the interpretation by the district court. The examiner further notes the extensive collection of prior art, including articles and patents, submitted in various information disclosure statements.

7. Based upon the intrinsic record, the term "longitudinally flexible" means "flexible relative to the longitudinal axis."

7a. More specifically, within the context of the claims themselves, the term is not further defined except that the stent must be implantable in a body lumen. In claims 1 and 12, the term "longitudinally flexible" appears in the first line (in the preamble) and last line of the claims. In the preambles, it appears in the following context:

> "A longitudinally flexible stent for implanting in a body lumen, ..."

In the body of the claim, the term appears in the last limitation as follows:

> "a weld connection between each cylindrical ring to attach the plurality of cylindrical rings along the common longitudinal axis thereby forming the longitudinally flexible stent." (claim 1)
>
> "a weld connection for attaching one peak of one cylindrical ring to an adjacent peak of an adjacent cylindrical ring so that the plurality of cylindrical rings are attached along the common longitudinal stent axis thereby forming the

longitudinally flexible stent." (claim 12)

The lumen's size or type is not specified. There is no requirement that the body lumen be "tortuous." Therefore, the degree of longitudinal flexibility is simply broadly recited with respect to the size or type of body lumen into which it is implanted.

7b. Next, the examiner considers the usage of the term within the specification. The following is an (hopefully) exhaustive listing (with emphasis added) of the term "longitudinally flexible" as it appears contextually in the specification:

> "One of the difficulties encountered using prior stents involved maintaining the radial rigidity needed to hold open a body lumen while at the same time maintaining the *longitudinal flexibility* of the stent to facilitate its delivery." (col. 1, ll. 46-49);
>
> "The present invention is directed to an expandable stent which is relatively *flexible along its longitudinal axis* to facilitate delivery through tortuous body lumens, ..." (col. 1, ll. 59-61);
>
> "The resulting stent structure is a series of radially expandable cylindrical elements which are spaced longitudinally close enough so that small dissections in the wall of a body lumen may be pressed back into position against the lumenal wall, but not so close as to compromise the *longitudinal flexibilities* of the stent. The individual cylindrical elements may rotate slightly relative to adjacent cylindrical elements without significant deformation, cumulatively giving a stent which is *flexible along its length and about its longitudinal axis* but is still very stiff in the radial direction in order to resist collapse." (col. 2, ll. 6-16);
>
> "The number and location of elements interconnecting adjacent cylindrical elements can be varied in order to develop the desired *longitudinal flexibility* in the stent structure both in the unexpanded as well as the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen which is internally supported by the stent. Generally, the greater the *longitudinal flexibility* of the stent, the easier and the more safely it can be delivered to the implantation site." (col. 3, ll. 10-20); and
>
> "The alternation of the interconnecting elements results in a stent which is *longitudinally flexible* in essentially all directions." (col. 5, ll. 46-48).

7c. Within the context of the specification, the inventor does not clearly and explicitly set forth a definition for "longitudinally flexible" anywhere in the specification. See item 7b above.

7d. Moreover, the specification does not imply, based upon the usage of the term in

the specification, that the term means "flexible along its length to facilitate delivery to tortuous body lumens." As discussed in Vitronics and Bell Atlantic, the court said that the specification can define terms "by implication." Vitronics at 1583 and Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001). In Bell Atlantic, terms were defined by relying on the definition implied in the specification by consistent usage. Bell Atlantic at 1271.

In the present case, within the specification, the term is modified only once by its ability to "facilitate delivery through tortuous body lumens." See item 7b above, second example. To differentiate from Bell Atlantic, this singular usage of the term hardly presents a consistent pattern. This singular usage of the term describes an example of the term. In other words, it describes a degree of flexibility.

8. Next the examiner considers the extrinsic record. The patent owner refers to an article by Duprat et al. See item 11 below. As noted in Phillips, "while extrinsic evidence 'can shed useful light on the relevant art,' we have explained that it is 'less significant than the intrinsic record in determining 'the legally operative meaning of claim language.' '" Phillips at 1317. (citations excluded) "This extrinsic evidence may be used only to assist in the proper understanding of the disputed limitation; it may not be used to vary, contradict, expand, or limit the claim language from how it is defined, even by implication, in the specification or file history." Bell Atlantic at 1269, citing Vitronics at 1584-85, 90 F.3d 1576, 39 USPQ2d at 1579.

9. As noted at item 2 above, "When interpreting a claim, words of the claim are generally given their ordinary and accustomed meaning, unless it appears from the specification or the file history that they were used differently by the inventor." In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994). As explained at items 7-7d above, the claim language is not defined within the claims themselves nor by implication in the specification. Thus, the next step is to look to the ordinary and customary meaning of the term.

10. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips at 1313.

11. At p. 23 of the POR, the patent owner refers to the article by Duprat et al. entitled

"Flexible Balloon-expanded Stent for Small Vessels" as evidence of how one of ordinary skill in the art would understand "longitudinally flexible." The article states:

> "We have also succeeded in inserting the self-expanding zig-zag stents into straight vessels smaller than 5 mm, but this stent has no longitudinal flexibility either (3). This flexibility is important if stents are to be inserted into small, continuously moving vessels with numerous curves and bends, such as the coronary arteries." (Duprat article, p. 277, third column)

At p. 24 of the POR, the patent owner refers to the declarations of Segal and Kahn submitted with the POR. As explained in both declarations, both Drs. Kahn and Segal understand the term "longitudinally flexible" as referring to stents that are "flexible along their length to facilitate delivery to tortuous body lumens" in agreement with the Duprat article (POR, p. 20, ll. 14-17). See the Kahn declaration, ¶ 24, and the Segal declaration, ¶ 15.

12. Besides the Duprat article (item 8 above), the term "longitudinally flexible" (or something similar) appears in various journal articles (with emphasis added) as follows:

> "One disadvantage inherent in this graft configuration is the lack of *longitudinal flexibility*, which limits its use to straight arterial segments or, in the case of curved arteries, requires the use of short graft lengths." (Palmaz et al. "Expandable Intraluminal Graft: A Preliminary Study" (Radiology, July 1985, p. 76, col. 1))
>
> "The relevance of the *longitudinal flexibility* of stents has been addressed repeatedly in the literature [8, 12, 14]. Although *flexibility along the longitudinal axis* is needed to navigate the stent through tortuous vessels ..." (Palmaz "Balloon-Expandable Intravascular Stent" (AJR, June 1988, p. 1264, col. 1))
>
> "A *longitudinal flexible* stent, which is also flexible even when mounted on its delivery catheter, will permit easier access through tortuous vessels to the target site." (Sigwart et al. "Intravascular Stents to Prevent Occlusion and Restenosis after Transluminal Angioplasty" (The New England Journal of Medicine, March 1987, p. 705, last four lines))
>
> "Although the principle is quite attractive, the relative rigidity of the device suggests that selective catheterization and stenting tight bends or long curves might be difficult." (Rousseau "Self-Expanding Endovascular Prosthesis: An Experimental Study"[1] (Radiology, Sept. 1987, p. 713, col. 3))
>
> "There is no question that any stent design must incorporate *flexibility* as a principal feature for coronary artery implantation. Not only must the stent pass easily through the guiding catheter, it must pass through tortuous coronary

[1] This citation is mentioned because "rigidity" is the opposite of "flexibility" and thus also demonstrates how "flexibility" was understood by those of ordinary skill in the art.

arteries to arrive reliably at the target site....
"A stent should be *flexible* enough to pass through narrow, tortuous passageways and yet, after expansion, still maintain a relatively stable, nonflexing, and nonshifting surface on which endothelial cells and neointima can grow most efficiently. One possible solution is shown in Figure 5. A modified Palmaz stent consisting of multiple short segments allows for 'articulation' around bends of both guiding catheters and coronary arteries, but once expanded, it becomes a stable surface. It is, therefore, *longitudinally flexible* but radially noncompliant. Preliminary animal and human trials suggest that such a device can be used in curved segments of coronary arteries without complication." (Schatz "A View of Vascular Stents" (Circulation, Feb. 1989, p. 449, col. 2))

"Despite improvements however, the Palmaz-Schatz stent remains relatively stiff and inflexible and is difficult to place in tortuous vessels." (Colombo et al. "Initial Experience With the Disarticulated (One-Half) Palmaz-Schatz Stent: A Technical Report" (Catheterization and Cardiovascular Diagnosis, April 1992, p. 304))

13. Moreover, as cited at p. 13 of the '8619 request, the following patents use the term (or something similar) as follows:

"Moreover, even assuming that the Patent Holder does amend its claims to import some narrower language into the claims (e.g., its proposed 'flexible along its length to facilitate delivery to tortuous body lumens'), such language is still insufficient to define over the prior art. As illustrated by the prior art submitted herewith, it was widely known and taught prior to the '167 Patent's effective filing date that stents were flexible along their length to facilitate delivery to tortuous body lumens.
The prior art literature is replete with teachings to that effect. Just for example, U.S. Patent No. 5,195,984 to Schatz ... discloses that his stent device 'provides the necessary flexibility to negotiate the bends and curves in tortuous body passageways, such as the vascular system.' Schatz col. 4, lns. 22-25 (emphasis added). And that '[b]ecause of the disposition of flexible connector members 100 between adjacent tubular members 71, or grafts, or prosthesis, 70' is able to flexibly bend, or articulate, with respect to the longitudinal axis of graft, or prosthesis, 70', so as to be able to negotiate the curves or bends found in body passageways 80. It should be noted that connector members 100 permit the bending, or articulation of adjacent tubular members 71 in any direction about the longitudinal axis of graft, or prosthesis, 70'.' Schatz col. 11, lns. 22-32 (emphasis added).
Similarly, U.S. Patent No. 5,102,417 to Palmaz ('Palmaz') ... discloses a device that 'provides the necessary flexibility to negotiate the bends and curves in the vascular system.' Palmaz col. 3, lns. 49 - 51. Palmaz explains that 'because of the disposition of flexible connector members between adjacent tubular members, the [stent] is able to flexibly bend, or articulate, with respect to the longitudinal axis.., so as to be able to negotiate the curves and bends found in body passageways.' Palmaz col. 12, lns. 41 – 47."

14. There are several reasons that the articles and the patents listed at items 11-13

above are accorded greater weight than the statements of Drs. Kahn and Segal in their declarations. It is appreciated that Drs. Kahn and Segal are persons of ordinary skill in the art. However, it is noted that the declarations of Drs. Kahn and Segal were made many years after the filing date of the subject patent. Neither of the declarants states that his understanding of the term was how one of ordinary skill would have understood it at the time of invention.

15. On the other hand, there are no memory issues associated with the patents and the articles. Moreover, with the exception of the Colombo article, the patents and articles predate the effective filing date of the subject patent[2], but are not so old and out-of-date so as to be considered archaic by one of ordinary skill in the art. Colombo was published very close in time to the effective filing date of the subject patent so as to be considered contemporaneous. Thus, the patents and articles are contemporaneous with the time of invention of the subject patent. What's more, since said articles and patents also predate any reexamination proceedings associated with the relevant family of patents (i.e., the family of the subject patent) and any litigation associated with said family, it cannot be said that said articles and patents are biased because they were generated in response to any such proceedings. Thus, based upon these facts, it appears that said articles and patents are reliable evidence as to how one of ordinary skill in the art would understand the term "longitudinally flexible."

16. Based upon the prevalent and consistent usage of the term "longitudinally flexible" (or something similar) in the articles and patents at items 11-13 above, said articles generated contemporaneously with the time of invention of the subject patent and by a number of different authors, the examiner concludes that the term "longitudinally flexible" in the context of stents had the following meaning to one of ordinary skill in the art at the time of the invention of the subject patent: flexible along the length of the stent such that the stent can be delivered to tortuous body lumens. This definition does not contradict the usage of the term in the specification.

17. Finally, at pp. 24 and 25 of the POR, the patent owner refers to the findings of

---

[2] Essentially, the effective filing date for the subject patent is 10/28/1991. See App. Serial No. 08/164,986. As per the originally filed specification in this application, p. 2, under the Summary of the Invention, "The present invention is directed to an expandable stent which is relatively flexible along its axis to facilitate delivery through tortuous body lumens."

the judge in the district court. More specifically, the court states,

> "the intrinsic evidence [i.e., specification], supports the conclusion that having longitudinal flexibility alone is not enough to meet the restriction of the Lau design; a stent must be flexible enough to be delivered through 'tortuous body lumens' before it will be considered to meet the 'longitudinally flexible' limitation of the Lau patents." (POR, p. 21, top)

While the examiner has considered the court's opinion, the examiner notes that different standards for claim interpretation are used in the Patent Office and the courts. See Trans Texas Holdings Corp. at 1298, citing Yamamoto at 1571.

"cylindrical rings"

18. At p. 25 of the POR, the patent owner argues that "cylindrical elements" and "cylindrically rings" excludes any structure that would be capable of functioning individually as a stent. At p. 15 of the '8619 request, the requester disagrees with the patent owner as follows: "'Cylindrical rings' is a self defining term that simply refers to a ring that is cylindrical in shape."

19. The examiner notes that neither the claims nor the specification of the subject patent defines the terms "cylindrical rings" or "cylindrical elements" in the manner advocated by the patent owner.

20. At p. 26 of the POR, the patent owner relies upon the prosecution history of U.S. Patent No. 5,514,154 (application no. 08/281,790), whose filing date the subject patent claims the benefit of under 35 U.S.C. 120, for the interpretation that "cylindrical ring" does not read on a functional stent.

21. The doctrine of prosecution history estoppel does not have a bearing on the Office's standard for claim interpretation. The Office is not required, in the course of prosecution (or reexamination of an unexpired patent), to interpret claims in the same manner as a court would interpret claims in an infringement suit. See In re Morris, 127 F.3d 1048 (Fed. Cir. 1997). In the present case, applying the "broadest reasonable interpretation" standard (see item 1 above), "cylindrical rings" or "cylindrical elements" is given its plain and ordinary meaning—an element that is cylindrical in shape.

22. At p. 28 of the POR, the patent owner again refers to the findings of the district court. In response, see item 17 above.

Statutory Bases for Claim Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Ex Parte Reexamination 90/007,890

23. At pp. 12-15 of the request in reexamination 90/007,890 (" '7890 request"), the requester suggested that Wolff anticipates claims 1-3 of the subject patent. The examiner agrees as explained herein.

Claims 1-7 and 12-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,104,404 to Wolff.

23a. Regarding claim 1, Wolff discloses the invention as claimed including a longitudinally flexible stent. As explained in Wolff, all of the embodiments include either hinges 14,22,42 or wires 32, "which effectively form the hinges" (col. 4, ll. 26 and 27). These hinges allow for articulation between the stent segments such that the stents can be used in curved blood vessels. See Wolff, claim 1, ll. 4-7. Moreover, according to Wolff's Field of the Invention, Wolff's stent is applied within coronary arteries. Coronary arteries have tortuous paths. Also according to Wolff's Field on Invention, "The invention relates particularly to arteries which have a curved portion, curved and

recurved portions." "Curved and recurved" is the same as "tortuous."

23b. Regarding claims 2-5, see Fig. 1.

23c. Regarding claim 7, see Figs. 1-5.

23d. Regarding claim 12, the rings 12 shown in Fig. 1 have an undulating pattern of peaks and valleys. Moreover, adjacent rings are out of phase with one another. As disclosed at the abstract, l. 2, Wolff discloses at least one weld connection between each cylindrical ring to attach the plurality of cylindrical rings along the common longitudinal axis thereby forming the longitudinally flexible stent.

Regarding claims 6 and 12, Fig. 11 of the subject patent is the only figure for which the rings/elements are described as and appear to be out of phase. Since the peaks of every ring are also the valleys, depending upon perspective, the pairs of portions of adjacent rings, which are connected by interconnecting elements 13, can be called "peaks." In this same manner, the peaks of one cylindrical ring of Wolff point towards the peaks of an adjacent ring.

23e. Regarding claim 13, see Fig. 8.

23f. Regarding claims 14 and 15, see Fig. 1.

23g. Regarding claim 16, the language "one of N-1 adjacent weld connections" is not exclusive. Since Wolff discloses two weld connections between adjacent rings, Wolff necessarily discloses one weld connection between adjacent rings.

24. At pp. 19, 31, 32, and 44 of the POR, the patent owner argues that Wolff does not disclose a stent that is "longitudinally flexible."

24a. At p. 19 of the POR, referring to Dr. Segal's declaration, the patent owner notes that the stent design of Wolff was "never commercialized" and was of an "impracticable" design. It is unclear how the lack of commercialization and the alleged impracticability is relevant to the consideration of whether or not Wolff anticipates the claims of the subject patent.

24b. Besides Dr. Segal's opinions (discussed below), the patent owner relies upon Wolff's deposition in an interference to demonstrate that the stents of the Wolff patent are not longitudinally flexible. See p. 19 of the POR. It is noted, however, that the referenced portion of the interference deposition appears to relate to an earlier prototype and not the particular stents depicted in the Wolff patent. See the deposition,

p. 116, ll. 18-20 ("I believe some of the alternative connection methods shown in the '404 patent are hinges to the extent that connecting member itself is in fact flexible. This particular first prototype the weld itself I described as being rigid."). It is unclear from the deposition whether or not the embodiments of the Wolff patent are also only marginally flexible and not longitudinally flexible.

24c. Also at p. 19 of the POR, again referring to Dr. Segal's declaration, the patent owner argues that since the individual stents of Wolff are inflexible, the entire stent of Wolff is likewise inflexible. In the declaration, the doctor opines that since the individual stents of Wolff are themselves substantially inflexible, and because any limited flexibility would occur only at the articulation points between those stents created by the hinges, the overall design would not be longitudinally flexible. See items 30 and 31 of the Segal declaration. Only Wolff's deposition supports this opinion. As noted at item 24b above, the portion of the deposition relied upon does not even appear to be relevant to the embodiments shown in Wolff's patent.

24d. Additionally, at p. 32 of the POR, the patent owner refers to the trial testimony of Medtronic's expert interventional cardiologist, Dr. Pearle. At p. 590, ll. 14-20 of his testimony, Dr. Pearle states:

> "I also think that this is a very different concept than having a stent that is inherently flexible along its length. When you combine two inflexible stents with a flexible connector you do not get a device that performs or is designed in the Wiktor '727 patent or the Multi-Link stent."

Dr. Pearle's testimony is only peripherally related to the current case because it relates to Gianturco stents and not Wolff's stent in particular. To the extent that this testimony applies to the teachings of Wolff, even if Wolff's stent is not "inherently flexible" to the same degree as Wiktor's or the Multi-Link stent, it does not necessarily follow that Wolff's stent is not "longitudinally flexible" as understood by those skilled in the art. The claims of the subject patent require longitudinal flexibility. Referring to item 16 above, the claim term "longitudinally flexible" means "flexible along the length of the stent such that the stent can be delivered to tortuous body lumens." As noted at items 24e and 24f below, the stent of Wolff, based upon its own disclosure meets this definition.

24e. Based upon Wolff's teachings in its specification, the examiner disagrees with Dr. Segal's opinion that since the individual stents of Wolff are themselves substantially

inflexible, and because any limited flexibility would occur only at the articulation points between those stents created by the hinges, the overall design would not be longitudinally flexible. More specifically, as explained in Wolff, all of the embodiments include either hinges 14,22,42 or wires 32, "which effectively form the hinges" (col. 4, ll. 26 and 27). These hinges allow for articulation between the stent segments such that the stents can be used in curved blood vessels. See Wolff, claim 1, ll. 4-7. Moreover, according to Wolff's Field of the Invention, Wolff's stent is applied within coronary arteries. Coronary arteries have tortuous paths[3]. Also according to Wolff's Field on Invention, "The invention relates particularly to arteries which have a curved portion, curved and recurved portions." "Curved and recurved" is the same as "tortuous."

24f. Thus, since the articulated stents of Wolff are for use in coronary arteries, which have tortuous paths, and relate to "curved and "recurved" arteries, which is synonymous with "tortuous," said Wolff stents are implantable in tortuous body lumens. Since said stents are implantable in these lumens, and are delivered to said lumens by PTCA (col. 1, ll. 11 and 2), it necessarily follows that they can be delivered through said lumens. Accordingly, the articulated stents of Wolff are flexible along their length such that the stent can be delivered to tortuous body lumens.

24g. In deciding whether or not Wolff's stent is longitudinally flexible as understood by those skilled in the art, the examiner considered the entire record. Having weighed Wolff's deposition in an interference (from which it is unclear whether or not the embodiments of the Wolff patent are also only marginally flexible and not longitudinally flexible), Dr. Segal's opinion, Dr. Pearl's testimony relating to Gianturco stents, as discussed at items 24b-24d above, against Wolff's clear disclosure that Wolff's stents are used in coronary arteries and "curved and recurved" arteries (item 24e above), the examiner concludes that evidence presented by the patent owner is not sufficient to outweigh the evidence of obviousness.

25. At p. 33 of the POR, the patent owner argues that Wolff does not disclose "cylindrically shaped elements." See items 18-21 above. Clearly, the segments 12 of Wolff are cylindrical, as the term is understood by skilled in the art, since the drawings

[3] Weinhaus et al. "Anatomy of the Human Heart." in Iaizzo, Paul A. (Ed.), "Handbook of Cardiac Anatomy, Physiology, and Devices" p. 73, Fig. 23 and p. 78, col. 1, ¶2.

show the use of segments from US Patent No. 4,830,003 (see col. 1, ll. 52-55). In this earlier patent, the stents are described as cylindrical. See the abstract of US Patent No. 4,830,003.

26. At pp. 15-17 of the '7890 request, the requester suggests that Wolff in combination with Boneau render obvious claim 11 of the subject patent. In the previous office action, the examiner rejected both claims 11 and 18 based upon this combination of references. Upon reconsideration, the rejection of claim 11 is withdrawn. See the explanation at item 31 below. The rejection of claim 18 is maintained, as explained herein.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,344,053 to Boneau in view of Wolff.

26a. Boneau discloses the invention substantially as claimed including a plurality of cylindrical rings (see col. 6, ll. 6-19) each having a diameter and a length. Claim 18 further requires that each of the cylindrical rings has a length less than the diameter thereof. At col. 5, ll. 4-22, Boneau discloses that the typical vessel, into which the stent of Boneau might be implanted ranges from 1.5 mm to 5 mm in diameter. Thus, since the cylindrical ring of Boneau is expanded to the vessel diameter (see Fig. 4), the diameter of the cylindrical ring of Boneau, in the expanded position, ranges from 1.5 mm to 5 mm. Boneau also discloses that corresponding stents may range from 1 mm to 2 cm in length, with a preferred length of 3.5-4.5 mm.

26b. At pp. 15-17 of the POR, the patent owner supplies evidence, in the form Dr. Segal's declaration, Dr. Stertzer's article ("The Applied VE Micro Stent"), and Dr. Kahn's declaration, that a stent shorter than 4 mm in length would be inoperative because it would not be able to maintain its axial orientation in the blood vessel. Taking this into account, the range of lengths taught by Boneau but not including the range less than 4mm (i.e., 4 mm-2cm). 4 mm (length) is less than 5 mm (diameter).

26c. Boneau does not disclose that the plurality of cylindrical rings are connected so as to be generally aligned on a common longitudinal axis and at least one weld connection between each cylindrical ring to attach the plurality of rings along the common longitudinal axis thereby forming the longitudinally flexible stent.

26d. As discussed at items 23a and 23d above, Wolff discloses a plurality of

cylindrical rings 12, which are connected so as to be generally aligned on a common longitudinal axis, with at least one weld connection between each cylindrical ring to attach the plurality of rings along the common longitudinal axis thereby forming the longitudinally flexible stent, and the peaks being out of phase. As discussed in the abstract, l. 14-18, the welded connections (hinges 14) provide articulation and spacing between the stent segments.

26e. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the device of Boneau with the welded hinges taught by Wolff for the purpose of providing articulation and spacing between cylindrical rings.

27. At pp. 14, 15, and 29-31 of the POR filed March 2007, relying upon the opinions of Dr. Segal in his declaration (see ¶25), the patent owner argues that Boneau teaches away from the combination. Weighing the evidence provided by the patent owner against the facts relied upon in the obviousness rejection above, the examiner disagrees.

27a. According to the decision in In re Gurley,

> "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994).

27b. In the current case, the patent owner and Dr. Segal refer to the following teachings from Boneau as evidence that this reference teaches away from a combination including connected stents:

> "[T]he stent should be short enough as to not introduce unnecessarily large amounts of material as might cause undue thrombosis." (col. 5, ll. 12-14)
>
> "Another object of the present invention is to provide a stent which does not result in significant thrombosis at the point of implant." (col. 3, ll. 50-52)
>
> "A still further object of the present invention is to provide a method for supplying an endovascular support device which permits a plurality of such devices to be implanted commensurate with the length of the lesion under treatment." (col. 3, ll. 56-59)

27c. It is noted that Boneau does not explicitly teach away from providing its stents

with connectors.

27d. With respect to the first two cited teachings of Boneau (item 27b above), the patent owner and Dr. Segal seem to be arguing that Boneau teaches away from the modification of Boneau's stents (i.e., adding connecting struts such as the hinges taught by Wolff) because such a modification would involve the use of more material, which would in turn increase the possibility of thrombosis. Referring to the first cited teaching at item 27b above, Boneau discussed thrombosis in relation to the size of the stent. Boneau does not teach that connectors themselves are undesirable. Moreover, Wolff teaches the desirability of providing connectors to separate adjoining stents to prevent interference between adjacent stents. Such interference would reduce effectiveness and increase procedure time. See Wolff, col. 1, ll. 35-39. On balance, the increased possibility of thrombosis caused by the added material of the connectors does not outweigh the desirability of providing connectors, as taught by Wolff, especially since Boneau does not discourage the use of connectors.

27e. With respect to the last cited teaching of Boneau (item 27b above), the patent owner and Dr. Segal seem to be arguing that Boneau teaches away from the modification of Boneau's stents because Boneau teaches implanting a plurality of stents. However, there is nothing in this teaching that discourages providing said stents with connectors.

28. At pp. 31 and 32 of the POR, the patent owner argues that the combination of Boneau and Wolff would not result in a longitudinally flexible stent because the individual stents of both Wolff and Boneau are inflexible. In response, see items 24-24g above.

29. At pp. 32 and 33 of the POR, the patent owner argues that real-world evidence shows that it would not have been obvious to connect together multiple Boneau stents. The patent owner suggests that since Mr. Boneau and his co-inventors did not file for a patent application directed to welding several Boneau stents together until 1994, that connecting multiple Boneau stents together involves the use of impermissible hindsight. However, since Wolff expressly discloses a motivation (providing articulating and spacing, see item 26d above) for providing connectors between multiple stent units, clearly hindsight has been avoided.

30. At pp. 33-36 of the POR, the patent owner argues that since both Wolff and Boneau teach functional stents, they do not teach cylindrical rings. In response, see items 18-22 above. Since the individual stents of Wolff and Boneau are cylindrical in shape, they meet the requirements of the claim.

31. The examiner withdraws the rejection of claim 11 based upon Boneau (in combination with Wolff) that was made in the previous office action. At pp. 36 and 37, the patent owner argues that Boneau does not teach or suggest the diameter of the Boneau in the "unexpanded and uncrimped configuration" and a cylindrical ring that has a length less than its diameter in that configuration. The examiner agrees with the owner that the rejection applying Boneau was speculative since Boneau does not discuss dimensions of Boneau's stent in the "unexpanded and uncrimped configuration." As explained in the previous office action at item 10, Boneau further discloses that the stent may have between two and ten turns. See col. 6, l. 19. At col. 4, ll. 58-60, Boneau discloses a wire diameter in the range of 0.002 to 0.025 inches. Based upon the ranges of the turns and the wire diameter, the diameter of the ring in a crimped position can range from 0.064 to 4.044 mm. However, the range of 0.064 to 4.044 mm actually represents the stent compressed to its absolute smallest size as limited by the numbers of turns and the wire diameter. According to Boneau, the crimped position appears to be controlled by the size of the balloon. See Boneau, col. 5, ll. 23-25 and Fig. 2. However, Boneau does not disclose the size of the balloon in the uninflated position. Thus, the diameter of the stent in the crimped position of Boneau cannot be ascertained and the rejection cannot be maintained.

32. At pp. 17-19 of the '7890 request, the requester suggests that Furui (article: "Hepatic Inferior Vena Cava Obstruction: Treatment of Two Types with Gianturco Expandable Metallic Stents") "clearly anticipates" claims 1-3 of the subject patent. The examiner disagrees as explained herein.

32a. Upon reconsideration, the examiner withdraws the rejection based upon Furui that was made in the previous office action because the tandemly connected stents of these references are not "flexible" as the term is understood by one of ordinary skill in the art. It was noted in the previous office action that the stent of this reference is flexible to at least some degree due to the flexibility necessary for expansion of the

individual stent segments. However, it does not necessarily follow that the stent of this reference is flexible as understood by those skilled in the art. It is further noted that Furui's stent was placed in the inferior vena cava. The inferior vena cava is a relatively straight blood vessel. See plate 248 of the book Atlas of Human Anatomy by Frank Netter. Finally, while it requires a certain amount of flexibility for implantation, it does not follow that implantation into the inferior vena cava requires "flexibility" as understood by those skilled in the art.

33. At pp. 20-26 of the '7890 request, the requester suggests that both US Patent No. 5,133,732 to Wiktor and US Patent No. 4,733,665 to Palmaz anticipate claims 1-3. The examiner disagrees as explained herein.

33a. Wiktor and Palmaz do not disclose a plurality of cylindrical rings. With respect to this claim requirement, the requester relies on Fig. 7 of Wiktor (see p. 20 of the request) and Fig. 2B of Palmaz (see p. 24 of the request). However, Fig. 7 of Wiktor shows one continuous spiral and not a plurality of rings. Elongate members 78 and 79 in Fig. 2B of Palmaz do not amount to a plurality of rings. At page 4 of the decision ordering reexamination, the examiner stated Wiktor discloses a plurality of rings. However, after reconsideration, the examiner concedes that construing randomly chosen sections of a coil as a plurality of cylindrical rings, as shown in the figure at page 20 of the request, is not a reasonable position to take.

Ex Parte Reexamination 90/008,619

34. At pp. 22-31 of the '8619 request, the requester suggests that Irie (article: "Relocatable Gianturco Expandable Metallic Stents") anticipates claims 1-8, 12, and 14 of the subject patent. With regard to claim 8, the examiner disagrees. See item 35 below. With regard to claims 1-7, 12, and 14, the examiner agrees, as explained herein.

Claims 1-7, 12, and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Irie (article: "Relocatable Gianturco Expandable Metallic Stents").

34a. Regarding claim 1, Irie discloses the invention as claimed including a longitudinally flexible stent for implanting in a body lumen. In the abstract, Irie discloses, "the second [design] had short struts and more flexibility and was better suited for use in curved strictures." At p. 576, col. 1, ll. 18-20, with respect to the same

short strut second design, Irie discloses, "One side of each strut had a hinged structure, which gave the stent more flexibility (Fig 3)." Finally, Fig. 3 illustrates a flexing stent including two cylindrical elements. Based upon this disclosure, the stent of Irie is flexible along its length such that the stent can be delivered to tortuous body lumens.

34b. In Fig. 2a, Irie further discloses cylindrically rings generally aligned on a common longitudinal axis. As shown in Fig. 4, the rings are expandable in the radial direction.

34c. Finally, at p. 576, col. 1, ll. 21-23 of Irie, it is disclosed that the stents are connected with silver solder. According to the book Joining of Material and Structures, From Pragmatic Process to Enabling Technology (cited in the previous office action), "In its broadest sense, welding includes any process that causes materials to join through the attractive action of interatomic or intermolecular forces, as opposed to purely macroscopic or even microscopic mechanical interlocking forces. Thus, welding ..., brazing ..., soldering ..., and even adhesive bonding ... can all be considered 'welding' processes by the preceding definition." See p. 285. This same book refers to brazing and soldering as subclassifications of welding. See pp. 351 and 391. Thus, since the joint shown in Irie is a solder joint, and soldering is a subclassification of welding, the joint is necessarily a welded joint.

34d. Regarding claims 2-5, in Fig. 2b, Irie shows a "generally sinusoidal pattern" wherein the pattern of the rings is continuous, the pattern is comprised of a plurality of peaks and valleys, and the plurality of peaks of the rings are out of phase.

34e. Regarding claim 6, Fig. 3 of Irie shows a hinged end of the strut (towards the right) and an opposite non-hinged end. Based upon the globular mass at the non-hinged end, at least this end has weld connections. These weld connections are at the peaks of the rings.

34f. Regarding claim 7, Fig. 2b shows that the struts are circumferentially offset from one ring to the next. Thus, the weld connections are also circumferentially offset.

34g. Regarding claim 12, the rings shown in Fig. 2a have an undulating pattern of peaks and valleys. Moreover, adjacent rings are out of phase with one another. As discussed at item 34c above, Irie discloses at least one weld connection between each cylindrical ring to attach the plurality of cylindrical rings along the common longitudinal axis thereby forming the longitudinally flexible stent. Regarding the requirement that the

peaks are out of phase and the peaks of one ring point toward the peaks of an adjacent ring, Fig. 11 of the subject patent is the only figure for which the rings/elements are described as and appear to be out of phase. Since the peaks of every ring are also the valleys, depending upon perspective, the pairs of portions of adjacent rings, which are connected by interconnecting elements 13, can be called "peaks." In this same manner, the peaks of one cylindrical ring of Irie point towards the peaks of an adjacent ring.

34h. Regarding claim 14, see Fig. 2 of Irie.

35. Regarding claim 8, at p. 28 of the '8619 request, the requester suggests that Irie anticipates this claim. However, Fig. 2a, as annotated by the requester at p. 28 of said request, does not show the weld connections attaching *adjacent* rings.

Secondary Considerations

Commercial Success

36. In order to traverse the obviousness previous rejection of claims 11 and 18 (only the rejection of claim 18 has been maintained, see items 26-26e above), the patent owner submitted a declaration from Mark Murray regarding the commercial success of the Multi-Link[4] stent with the response filed March 23, 2007. The declaration relies upon the graph "Coronary Stent Market (1997-2003)" and the Wall Street Journal article "Missing a Beat: How a Breakthrough Quickly Broke Down for Johnson & Johnson" (9/18/1998). At pp. 37-39 of the POR, the patent owner discusses the evidence of commercial success of the Multi-Link stent with respect to the obviousness rejection. Finally, at items 51-56 of the Segal declaration, Dr. Segal also discusses the commercial success of the Multi-Link stent.

37. Based upon the chart ("Coronary Stent Market (1997-2003)") and the Wall Street Journal article (p. 1: "'Within 45 days, we had gained a 70% market position,' says Ronald W. Dollens, Guidant's president and chief executive officer. J.P. Morgan analyst Michael Weinstein characterizes the shift as 'the most dramatic transfer of wealth between two companies in medical-device history.'" And, "Now, as the annual U.S.

[4] "It is my understanding that Lilip Lau is a named inventor on the patents at issue in this proceeding, namely U.S. Patent Nos. 5,514,154; 6,066,167; 6,066,168; and 6,432,133. It has always been my understanding that the commercial product referred to as the 'Multi-Link' family of stents is based upon the design developed by Lillip Lau and his colleagues and described within those patents." Murray Dec., item 7.

market for stents surges past $1 billion, Guidant shares more than 80% of it ..."), the Multi-Link stent undoubtedly achieved commercial success. What is unclear is whether or not the commercial success was directly derived from the claimed invention. In other words, the patent owner has not sufficiently established a nexus between the claimed invention (i.e., claim 18 of the subject patent) and the commercial success of the product (i.e., the Multi-Link stent).

38. According to Demaco Corp. v. F. Von Langsdorff Licensing Ltd.,

> "When a patentee asserts that commercial success supports its contention of nonobviousness, there must of course be a sufficient relationship between the commercial success and the patented invention. The term 'nexus' is often used, in this context, to designate a legally and factually sufficient connection between the proven success and the patented invention, such that the objective evidence should be considered in the determination of nonobviousness. The burden of proof as to this connection or nexus resides with the patentee. *See, e.g., Cable Electric Products, Inc. v. Genmark, Inc .*, 770 F.2d 1015, 1027, 226 USPQ 881, 888 (Fed. Cir. 1985)."

Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed. Cir. 1988).

39. According to item 29 of the Murray declaration, "analyst reports indicated that consumers were purchasing the Multi-Link stent because of its superior design and deliverability." According to item 31, "We heard over and over from physicians that the Multi-Link was far more deliverable than competing stents, while not compromising radial strength and favorable clinical outcomes." Moreover, at item 56 of his declaration, Dr. Segal states, "In my opinion, the primary reason the Multi-Link, BX Velocity, NIR, and Medtronic Connected-ring stents (e.g., MicroStent II, GFX, S670, etc.) have achieved success among cardiologists is that they are longitudinally flexible, unlike first-generation designs such as the Palmaz-Schatz and peripheral stents such as the Gianturco Z-stents described in Mirich et al., Lawrence et al., Furui et al., and Rosch et al., while not compromising radial strength." These statements and opinions are unsubstantiated and have been accorded little weight. Moreover, these statements and opinions along with the rest of Murray's declaration do not provide any evidence that the commercially successful product owed its success to the invention of claims 11 and 18.

40. Based upon the record before the examiner, it appears that the Multi-Link stent does not owe its commercial success to the features of claim 18 of the subject patent. More specifically, footnote 10 at the bottom of p. 38 of the POR states, "Patent Holder does not contend that the Multi-Link practices the '168 claims." This statement shows that the commercially successful Multi-Link stent did not owe its success to the features of claim 18 of the subject patent. As such, the patent owner has not made a sufficient showing of nexus between the invention of claim 18 and the commercially successful Multi-link stent.

41. According to Murray's declaration, various other second generation stents also achieved commercial success. Further according to the declaration, the designs of these stents were similar to the Multi-Link stent. See items 23, 26, and 28 regarding J&J/Cordis' BX Velocity stent, Medtronic/AVE's Microstent II and GFX stents, and Boston Scientific's NIR stent. The commercial success of these stents is discussed below.

42. At items 23 and 28 of Murray's declaration, Mr. Murray discusses J&J's BX Velocity stent and Boston Scientific's NIR stent. According to the declaration, both companies took licenses to the Lau patents, which include the subject patent, to sell their respective stents. The Federal Circuit discussed the persuasiveness of licenses as evidence of commercial success, reiterating that "affirmative evidence of nexus [is required] where the evidence of commercial success presented is a license, because it is often 'cheaper to take licenses than to defend infringement suits.'" Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1342 (Fed. Cir. 2004). Here, the patent owner does not discuss the terms of the licenses or the relevant circumstances under which they were taken. There is no evidence that the BX Velocity stent and the NIR stent include the elements of claim 18. In item 23, Mr. Murray states that it is his opinion that the BX Velocity stent was commercially successful due to its flexibility and radial strength. However, other than this opinion, there is no evidence that the commercial success of the BX Velocity stent was due to the elements of claim 18. Regarding the NIR stent, there is likewise no evidence that the commercial success of this stent was due to the elements of claim 18.

43. A jury found that Medtronic's stents infringed claim 11 of the subject patent. See p. 2 of the Jury Verdict form for ACS v. Medtronic. According to said form, the jury

found that every one of Medtronic's listed stents, with the exception of the Microstent II, infringed claim 11. Moreover, as discussed at item 27 of the Murray declaration, which referred to the "Coronary Stent Market (1997-2003)" graph, Medtronic/AVE's market share rose quickly after introducing the Microstent II and the GFX stents. However, no evidence is presented connecting the commercial success of the infringing GFX stents to the elements of claim 11.

44. At p. 39 of the POR, the patent owner argues that since a jury found that Medtronics/AVE's stents infringed claims 1, 3, and 11 of the subject patent, there is a prima facie nexus between the claimed invention and the commercial success of the Medtronic/AVE stents. For support, the patent owner quotes from In re GPAC, which quotes Demaco Corp. V. F. Von Langsdorff Lic., Ltd., as follows "A prima facie case of nexus is generally made out when the patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent."

45. However, it does not necessarily follow from the fact that infringement was found that the commercially successful product is the invention of claim 18 of the subject patent especially since it appears that the verdict was silent with respect to claim 18. As noted at item 41 above, the commercially successful products are the Multi-Link stent and various other second generation stents. However, based upon the current record, the Multi-Link stent does not include the elements of claim 18. See footnote 10 at p. 38 of the POR. With regard to the infringing stents, it is unclear whether or not the elements of claim 18 of the subject patent led to the commercial success of these stents.

46. Moreover, in Ex parte Remark, the BPAI found the shifting of burdens of civil litigation in Demaco, which is quoted by In re GPAC, inapplicable in *ex parte* proceedings as follows:

> "In Demaco, the court stressed that the foregoing evidentiary routine of shifting the burden of coming forward with evidence in rebuttal after a prima facie case of nexus is established was appropriate in civil litigation, presumably because the challenger or adversary has the opportunity through discovery proceedings and other evidence gathering means to adduce such rebuttal evidence.
>
> In contrast, the examiner in ex parte proceedings has no available means for adducing evidence to show that the commercial success was due to extraneous factors. For this reason, we are of the opinion that the evidentiary routine

> pertaining to the shifting of the burden upon presenting a prima facie case of nexus is inapplicable to ex parte proceedings in the Patent and Trademark Office."

Ex Parte Remark, 15 USPQ2d 1498, 1503 (BPAI Jan 25, 1990). See also In re Huang, 100 F.3d 135, 139-140 (Fed. Cir. 1996). Thus, in the case of this *ex parte* proceeding, that there is commercial success and infringement of at least claim 11 does not establish prima facie commercial success.

47. At item 29 of his declaration, Mr. Murray offers opines, "In my opinion, ACS's marketing efforts from 1997-2000 were neither extraordinary nor unusual for the industry, and certainly did not surpass those of J&J." However other than Mr. Murray's opinion as to the relative marketing efforts of J&J and ACS, Mr. Murray offers no evidence that the commercial success of the Multi-link stent was not due to marketing. Since the price of the Multi-Link was actually greater than the average price of competitive stents (item 30 of Murray dec.), the success of the Multi-Link stent is not attributable to its selling price. However, other extraneous factors may have contributed to the stent's success. For example, there was resentment by customers towards J&J because of its previous rigid pricing (see the Wall Street Journal article). This resentment coupled with the opportune shift of rates by insurers and Medicare (WSJ article, last page) may have contributed to the commercial success of second-generation stents such as the Multi-Link stent.

48. The examiner agrees that the Multi-Link stent and other second generation stents were commercially successful. It may well be that customers flocked to the second generation stents, such as the Multi-Link stent, because of their superior flexibility and radial strength. However, the evidence of record fails to show a nexus between said commercial success and the invention of claim 18. As such, the declaration asserting commercial success is insufficient to overcome the obviousness rejection of claim 18.

Long-Felt Need and Failure of Others

49. At pp. 40-44 of the POR, the patent owner asserts the secondary consideration of Long-Felt Need and Failure of Others to overcome the obviousness rejection of claims 11 and 18. In his declaration, Dr. Kahn discusses long-felt need at items 17-19. Dr. Segal also discusses long-felt need at items 45-49.

50. In the same manner as the commercial success secondary consideration, the

secondary consideration of long-felt need and failure of others requires a nexus between the claimed invention (in this case, the elements of claim 18) and evidence of long-felt need. See In re Comiskey, 84 USPQ2d 1670, 1681 (Fed. Cir. 2007). At p. 43 of the POR, the patent owner states, "ACS solved the problem in 1991 with the connected-ring design (which is disclosed and claimed in the '168 patent), whereas it took Johnson & Johnson/Cordis and Medtronic/AVE several more years (and several failed designs) to arrive at the same solution." However, the patent owner offers no evidence that ACS's product, which met the long-felt need for a stent having longitudinal flexibility and radial strength, includes the elements of claim 18. Nor is any evidence offered that the elements of claim 18 actually solve the need. Thus, the evidence of record fails to show the requisite nexus between the evidence of long-felt need and failure of others and the invention of claim 18. As such, the evidence discussed in the POR with regard to long-felt need and failure of others is insufficient to overcome the obviousness rejection of claim 18.

Statement of Reasons for Patentability and/or Confirmation

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding:

51. Regarding **claim 8**, the prior art of record does not disclose, singly or in combination, the combination of elements recited in claim 8 including the weld connections attaching adjacent cylindrical rings being circumferentially aligned along the longitudinal axis. See also item 35 above.

52. Regarding **claims 9 and 10**, the prior art of record does not disclose, singly or in combination, the combination of elements recited in claim 9 including only one weld connection attaching adjacent cylindrical elements to each other.

53. Regarding **claim 11**, see item 31 above.

54. Regarding **claim 17**, the prior art of record does not disclose, singly or in combination, the combination of elements recited in claim 17 including each weld connection being circumferentially offset from the adjacent weld connections.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for

Patentability and/or Confirmation" and will be placed in the reexamination file.

Conclusion

55. The examiner requests that the patent owner submit another copy of the graph "Coronary Stent Market (1997-2003) since the data associated with Cordis is not clearly shown on the Office's copy. In evaluating Mr. Murray's declaration with respect to Cordis, the examiner considered the numbers presented in the declaration itself and the Wall Street Journal article. However, for purposes of creating a clear record, the examiner requests a clear copy.

56. In the future, the examiner further requests that both parties label their exhibits on the first page of each exhibit since the separating sheets normally used to label exhibits tend to get separated from the exhibits when scanned. The examiner requests that the label include the following information: (1) paper to which the exhibit is attached (e.g., Smith declaration or Patent Owner's response), (2) the exhibit's letter or number (e.g., Exhibit J), and (3) the title of exhibit.

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

Extensions of time in reexamination proceedings are provided for in 37 CFR 1.550(c). A request for extension of time must be filed on or before the day on which a response to this action is due, and it must be accompanied by the petition fee set forth in 37 CFR 1.17(g). The mere filing of a request will not effect any extension of time. An extension of time will be granted only for sufficient cause, and for a reasonable time specified.

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 6,066,168 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination

proceeding. See MPEP §§ 2207, 2282 and 2286.

Any paper filed with the Office, *i.e.,* any submission made, by either the patent owner or the third party requester **must** be served on every other party in the reexamination proceeding in the manner provided by § **1.248**. The document must reflect service or the document may be refused consideration by the Office. See 37 CFR 1.550(f).

The patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding **MUST** comply with 37 CFR 1.530(d)-(j), 37 CFR 1.52(a) and (b), and 37 CFR 1.20(c).

Amendment practice under 37 CFR 1.530(d)-(j) differs from that under 37 CFR 1.121. Please refer to MPEP § 2250, especially the examples. The following is provided for convenience:

Whenever there is an amendment to the claims, there must also be supplied, on pages separate from the pages containing the changes, (a) the status (i.e., pending or canceled), as of the date of the amendment, of all patent claims and of all added claims, and (b) an explanation of the support in the disclosure of the patent for the changes to the claims made by the amendment paper.

Whenever there is an amendment to the claims, the following status identifiers should be used: "(Original)" and "(Amended)," as appropriate. While it is not necessary, for new claims, the status identifier "(New)" may be used. Additions are shown by underlining and [deletions] are shown with single, square brackets. For new claims, the entire text of the proposed new claim must be underlined throughout, including the claim number and the status identifier, if used. It is preferable that cancelled claims be presented as follows: "Claims 1-5 (Cancelled)" within the listing of claims. The text of the cancelled claim surrounded by brackets should not be presented.

All changes must be shown relative to the patent under reexamination. For any subsequent amendments, additions and deletions must be shown relative to the issued patent, NOT relative to any previous amendment. These additions and deletions should be presented in the manner set forth in the paragraph above.

If an unamended base patent claim (i.e., a claim appearing in the reexamination as it appears in the patent) has been canceled, any claim which is directly or indirectly

dependent thereon should **NOT** be rewritten in independent form. Whereas, if a new base claim (a base claim other than a base claim appearing in the patent) has been canceled, a claim which depends thereon should be rewritten in independent form. See MPEP § 2260.01.

Contact Information

All correspondence relating to this *ex parte* reexamination proceeding should be directed as follows:

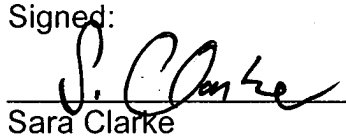
By **U.S. Postal Service Mail**: Mail Stop *Ex Parte* Reexam
Attn: Central Reexamination Unit
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-9900
Central Reexamination Unit

By hand: Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulany Street
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:



Sara Clarke
Primary Examiner
Central Reexamination Unit
(571) 272-4873

NOTICE RE PATENT OWNER'S CORRESPONDENCE ADDRESS

Effective May 16, 2007, 37 CFR 1.33(c) has been revised to provide that:

The patent owner's correspondence address for all communications in an *ex parte* reexamination or an *inter partes* reexamination is designated as the correspondence address of the patent.

Revisions and Technical Corrections Affecting Requirements for Ex Parte and Inter Partes Reexamination, 72 FR 18892 (April 16, 2007)(Final Rule)

The correspondence address for any pending reexamination proceeding not having the same correspondence address as that of the patent is, by way of this revision to 37 CFR 1.33(c), automatically changed to that of the patent file as of the effective date.

This change is effective for any reexamination proceeding which is pending before the Office as of May 16, 2007, including the present reexamination proceeding, and to any reexamination proceeding which is filed after that date.

Parties are to take this change into account when filing papers, and direct communications accordingly.

In the event the patent owner's correspondence address listed in the papers (record) for the present proceeding is different from the correspondence address of the patent, it is strongly encouraged that the patent owner affirmatively file a Notification of Change of Correspondence Address in the reexamination proceeding and/or the patent (depending on which address patent owner desires), to conform the address of the proceeding with that of the patent and to clarify the record as to which address should be used for correspondence.

Telephone Numbers for reexamination inquiries:

Reexamination and Amendment Practice	(571) 272-7703
Central Reexam Unit (CRU)	(571) 272-7705
Reexamination Facsimile Transmission No.	(571) 273-9900